FINAL REPORT OF THE STUDY

"A CLINICAL STUDY TO EVALUATE THE EFFICACY OF A POLY HERBAL FORMULATION (VIGOR-100-STAMINA) IN THE MANAGEMENT OF HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD)''

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INTRODUCTION

The words “Hypoactive Sexual Desire Disorder (HSDD)” is defined by the American Psychiatric Association as a persistent or recurrent deficiency or absence of sexual fantasies and desire for sexual activity that causes marked distress or interpersonal difficulty. For a diagnosis of HSDD to be given, the desire problem must not be better accounted for by another psychiatric disorder (e.g., depression), substance (e.g., a medication), or medical condition.

There are many risk factors and causes associated with Hypoactive Sexual Desire Disorder. If we consider sexual health and function from a holistic perspective, it is not surprising that mental health disorders, and physical ailments, can cause sexual dysfunction. In terms of mental illness, an actual symptom of depression is loss of interest in activities that were previously enjoyed, one of which can be sex. Additionally, anxiety can also impact sexual function. Certainly, marital discord or relationship disharmony, can also take its toll on sexual desire.

There are no such drugs in modern science to develop sexual desire in human being but the ancient treaties of Ayurveda describe some drugs under aphrodisiac categories which develop the sexual desire as well potency. The trial drug poly herbal compound (Vigor-100-stamina) having such potency, containing some aphrodisiac drugs like- Kapikachhu, Shilajit, Mushli, Aswagandha, Samudra Sosha, Jaiphala, Jaipatri, Dalchini, Akarakara, Lavanga, Keshara, Louha bhasma and Swarna bhasma etc. and processed by triturating with Brahmi, Yasthimadhu, Chandan, Satavari and Beetle.

EPIDEMIOLOGY & PREVALENCE OF HSDD

In 1999, The National Health and Social Life Survey (NHSLS) assessed sexual functioning among men and women in the U.S. The survey reported that 43% of women experienced some type of sexual dysfunction compared to only 31% of men. In women, the most common complaint was low sexual desire (22%) (women Laumann et al, 1999). In 2005, The Global Study of Sexual Attitudes and Behaviors (GSSAB) found similar results in a larger-scaled international survey of sexual problems among men and women in between 40 to 80 years of age. The GSSAB found that 26% to 43% of experienced low sexual desire compared to 13% to 28% of men (Gingell et al., 2005).

Drug Review

The trial drug is a “poly herbal compound (Vigor-100-Stamina capsule)” manufactured by Goodcare Pharma Pvt. Ltd., Bagi Mouza, Bishnupur, 24 Parganas and approved by Directorate of ISM Drugs control, Deptt. Of Health & F.W. Govt. of West Bengal and supplied by Goodcare Pharma Pvt. Ltd. 1, Gupta lane, Kolkata-700006.

The Trial drug Vigor-100 Stamina Contains 14 nos. of natural drugs (both Herbo-mineral origin) and processed by triturating in 6 juice and decoctions.

Each capsule contain-

1. Kapikachhu(Mucuna Prurita) – 148 mg. Ref- API, Vol-2 , P.g-46
2. Sodhita Silajatu (Asphaltum punjabinum) 50 mg. Ref- Bhabaprakash, Pg-370
3. Sweta musali (Cholorophytum borivillanum) 75 mg. Ref- Bhabaprakash, pg-391
4. Aswagandha(Withania somnifera) 60 mg. Ref-API, Vol-1 , Pg.-15
5. Dalchini (Cinamomum zeylanicum) 15 mg. Ref- Bhabaprakash, pg-118
6. Samudra sosha(Barringtonia acutangula) 20 mg. Ref- Bhabaprakash, pg-232
7. Salam mishri (Eulophia campestris) 20 mg. Ref- Bhabaprakash, pg-542
8. Jaiphal (Myristica fragrans) 15 mg. Ref- Bhabaprakash, pg-111
9. Jaipatri (Myristica fragrans) 15 mg. Ref- Bhabaprakash, pg-113
10. Akara kara (Anacyclus pyrethrum) 15 mg. Ref- Shaligram Nig., pg-37
11. Lavanga (Syzygium aromaticum) 15 mg. Ref- API, Vol- 1 , Pg- 80
12. Kesara(Crocus sativus) 6 mg. Ref- API, Vol- 4 , Pg- 52
13. Kanta louha Bhasma (oxide of iron) 6 mg. Ref- Ay. Sara Samg., pg-158
14. Swarna bhasma(oxide of gold) 1 mg. Ref- Siddha Yogasamg., Pg-15

All these drugs are processed in :-

1. Brahmi(Bacopa monieri) q.s. Ref-API, Vol-2, Pg- 25
2. Salmali twak (Salmalia malabarica) q.s. Ref-API, Vol-3, Pg- 183
3. Satavari(Asparagus racemosus) q.s. Ref-API, Vol-4, Pg- 108
4. Nagavalli (Piper beetle) q.s. Ref-API, Vol-3, Pg-131
5. Yasthimadhu (Glycyrrhiza glabra) q.s. Ref-API, Vol-1, Pg- 127
6. Sweta chandana(Santalum alba) q.s. Ref-API, Vol-3, Pg- 207

All the drugs present in the trial drugs are having Vajikara (Aphrodisiac), Rasayan (Rejuvenation) and Soumanasya Janana (Pleasant for Mind) properties and after triturating with the specify juice and decoction its properties enhances.

Apart from herbal drugs the trial drug contains two mineral drugs like Swarna bhasma 1 mg and louha bhasma 6 mg per capsule.

MATERIALS AND METHOD

Patients attending the OPD & IPD of Gopabandhu Ayurveda Mahavidyalaya & Hospital, Puri, and Odisha were screened for their Serum testosterone irrespective of their sex, religion, cast etc. Only those patients who fulfilled the inclusion criteria and were ready to give informed consent for the study were registered for the trial. A specially designed research case sheet was used for collecting and maintaining

different data. 40 patients were randomly allocated to the Trial group (TG) and were treated with the trial drug (Vigor 100 stamina capsule) for a period of 6 weeks. 10 patients were also randomly allocated to the Placebo group (PG) and were treated with the Placebo (wheat powder). Randomization was done by computerized Random number generator. The entire study was completed in a span of six months (August 2014 to January 2015).

SELECTION CRITERIA

INCLUSION CRITERIA

- Age- 35 - 55 years
- Legally married and having own sexual partner
- Sex- From both the sexes
- Patient having the sign and symptoms of HSDD causing interpersonal distress. Like:-
  - i) Loss of Frequency
  - ii) Loss of Desire
  - iii) Loss of orgasm
  - iv) Loss of ability
- Patients must be willing to provide informed consent.

EXCLUSION CRITERIA

- Age below 35 years and above 55 years
- Patient having any other systemic disorder and history of STD.
- Patient having diabetes and heart diseases.
- Patients having any other Endocrine disorder.
- After menopause.

CONCOMITANT MEDICATION

Concomitant medications were monitored throughout the study and recorded in the research case sheet. 40 patients took no other drugs, 2 took laxatives, 3 took non-steroidal anti-inflammatory drugs (NSAID), 4 took antacids, and 1 took antibiotics. Most of these medications were taken for very short periods. None of the patients took any known Hypo sexual diseases related medication other than trial drug and control drug.

INVESTIGATION

All patients were investigated for their Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS), Renal function test, Liver Function Test and Serum testosterone before starting and after the completion of the trial. All the tests were performed in NABL accredited laboratory.

STUDY DESIGN

The current study was design in two groups Gr-A (Trial group) and Gr-B (Placebo group). The study was started after obtaining the approval of the Institutional Ethical Committee (IEC). Informed written consent was obtained from every patient before registering them in to the trial.

DRUGS AND POSOLOGY

Trial Drug group: Vigor-100 stamina Capsule was orally administered to the patients in the trial group in a dose of 2 capsules twice in a day after principal meal followed by lukewarm milk for a period of 6 weeks.

Placebo Drug group: 2 Placebo capsules (Wheat powder) were orally administered to the patients of control group twice in a day after principal meal followed by lukewarm milk for a period of 6 weeks.

ASSESSMENT OF THE STUDY

Criteria of Assessment

The following objective and subjective criteria were follow to assess the improvement of the cases before and after treatments.

Serum testosterone, SDI-2 Scoring and NSS scale was done for every patient included in the trial before starting and after completion of the study. Change in these parameters were analysed to get the outcome of the study by using suitable statistical method. The normal reference range of serum testosterone was fixed as per the guideline of Medline Plus Medical Encyclopaedia (An online service provided by the U.S. National Library of Medicine & National Institutes of Health.

STATISTICAL ANALYSIS

The values of Serum testosterone, SDI-2 Scoring and NSS scale before and after treatment were compared using Students Paired t-test. If the p – value was found to be $< .05$ the result was interpreted as insignificant. If the p – value was found to be $< .01$ the result was interpreted as significant. If the p – value was found to be $< .001$ the result was interpreted as extremely significant. All the calculations were done by using Graph pad statistical software.

The overall benefit of the drug was assessed by a specially designed scoring system. A percentage change in before treatment (BT) & after treatment (AT) was

calculated for Serum testosterone, SDI-2 Scoring and NSS scale for every patient. A corresponding score equal to the percentage change was assigned for each observation. These individual scores were added to get a total score. The total score was interpreted as per the following.

Scores 100 – Excellent Result

Scores between 61 to 100 – Good Result

Scores between 21 to 60 – Satisfactory Results

Scores ≤ 20 – Unsatisfactory Result

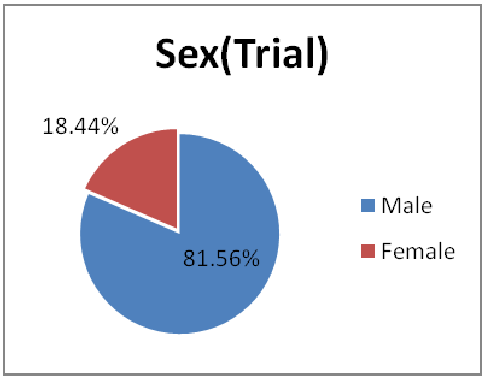
OBSERVATION & RESULT

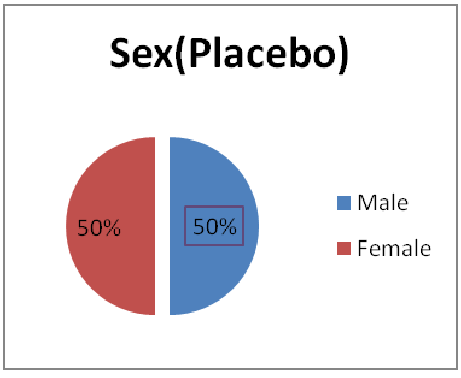
We registered 40 patients in Trial Group (TG) & 10 patients in placebo group (PG). But there was a drop out of 2 patients from TG due to different reasons and all patients of PG completed their treatments. Therefore 38 patients from TG and 10 patients from PG completed the trial.

DEMOGRAPHIC DATA

1. Sex Wise Distribution of Subject

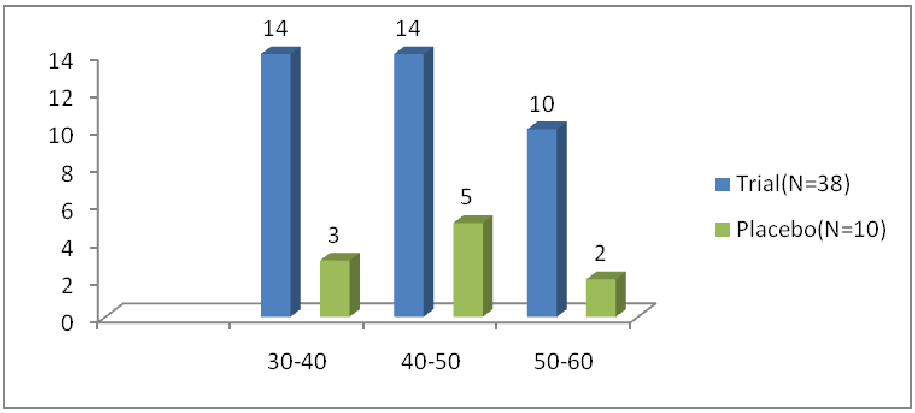
	Trial(N=38)		Placebo(N=10)	
Sex	No.	%	No.	%
Male	31	81.56	5	50
Female	7	18.44	5	50





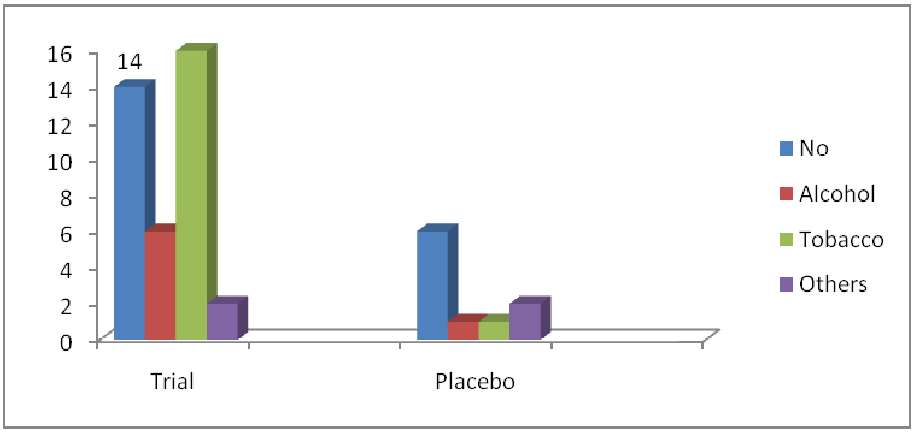
2. Age group wise distribution of Subject

Age group in years	Trial(N=38)		Placebo(N=10)	
	No.	%	No.	%
30-40	14	36.84	3	30
40-50	14	36.84	5	50
50-60	10	26.22	2	20



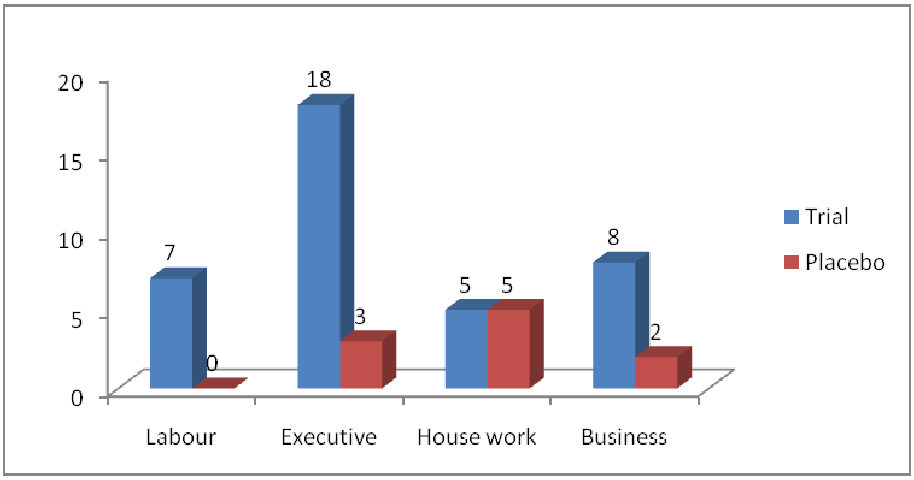
3. Addiction Wise Distribution of Subject

Addiction	Trial(N=38)		Placebo(N=10)	
	No.	%	No.	%
No	14	36.84	6	60
Alcohol	6	15.79	1	10
Tobacco	16	42.11	1	10
Others	2	05.26	2	20



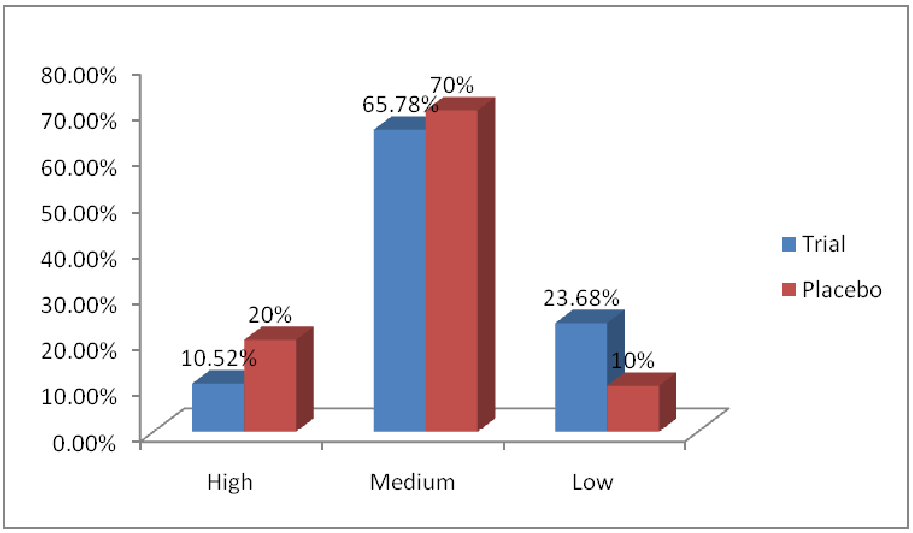
4. Occupation Wise Distribution of Subject

Occupation	Trial(N=38)		Placebo(N=10)	
	No.	%	No.	%
Labourer	7	18.42	0	0
Executive	18	47.36	3	30
House work	5	13.57	5	50
Business	8	21.05	2	20



5. Socio-economic status Wise Distribution of Subject

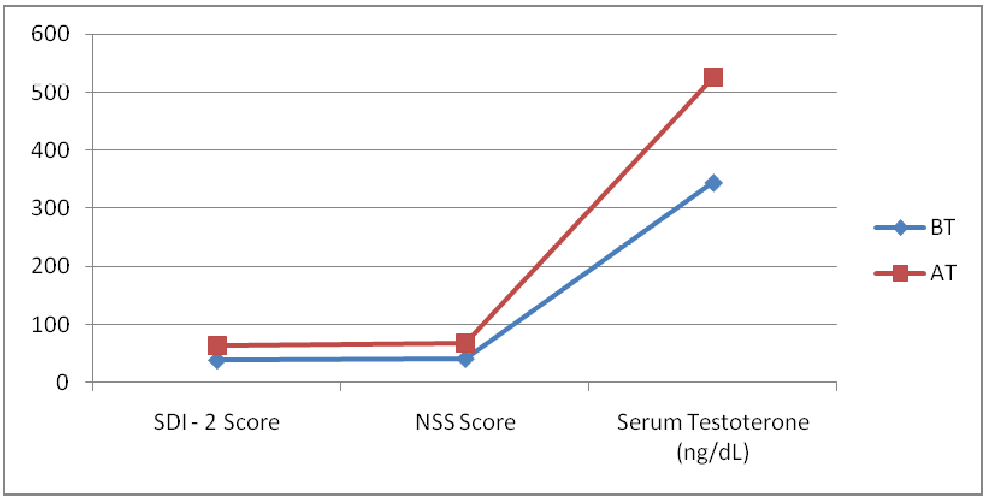
Socio-economic status	Trial(N=38)		Placebo(N=10)	
	No.	%	No.	%
High	4	10.52	2	20
Medium	25	65.78	7	70
Low	9	23.68	1	10



EFFECTIVENESS OF TRIAL DRUG AND PLACEBO DRUG

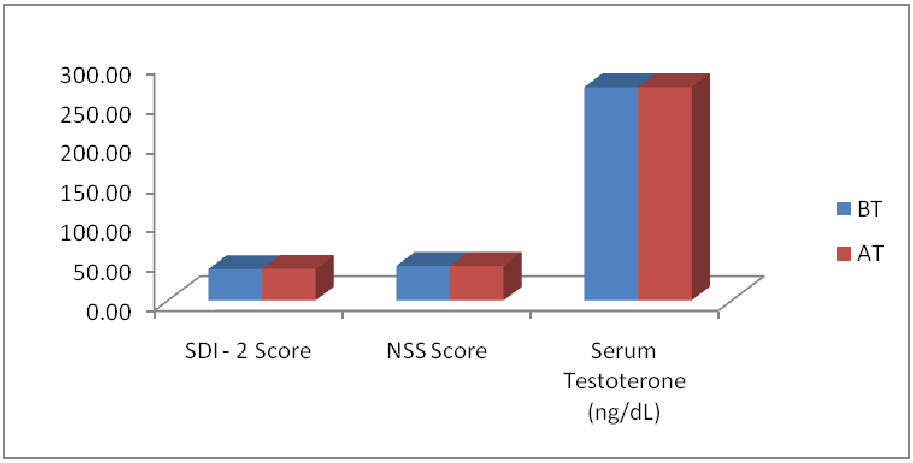
Trial Drug:-

Parameter	Frequency (n)	Degree of Freedom (df)	BEFORE TREATMENT (BT)		AFTER TREATMENT (AT)		↑	↓	t - Value	p - Value	Interpretation
			Mean (BT)	Standard Deviation (SD)	Mean (AT)	Standard Deviation (SD)					
SDI - 2 Score	38	37	38.82	6.22	63.34	6.75	↑		33.73	< 0.0001	Extremely Significant
NSS Score	38	37	41.34	6.25	67.63	5.86	↑		41.96	< 0.0001	Extremely Significant
Serum Testoterone (ng/dL)	38	37	344.67	185.88	525.99	255.33	↑		3.54	0.0007	Extremely Significant



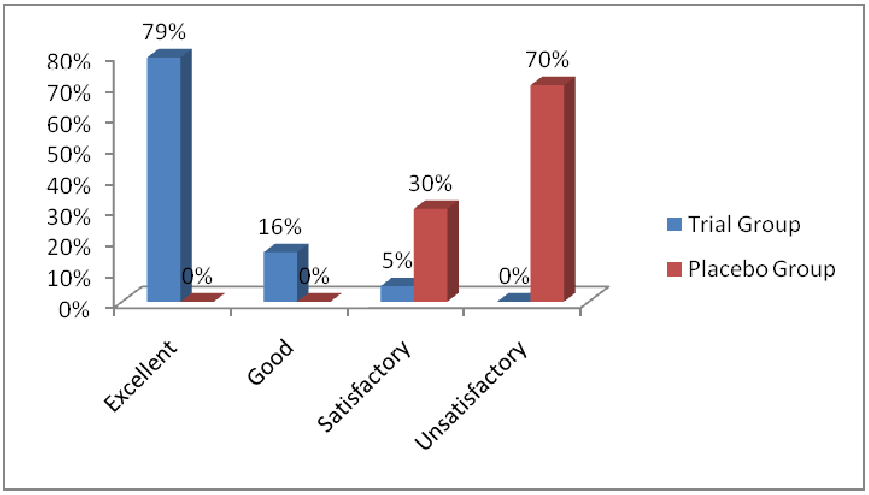
Placebo Drug:-

Parameter	Frequency (n)	Degree of Freedom (df)	BEFORE TREATMENT (BT)		AFTER TREATMENT (AT)		↑	↓	t - Value	p - Value	Interpretation
			Mean (BT)	Standard Deviation (SD)	Mean (AT)	Standard Deviation (SD)					
SDI - 2 Score	10	9	39.50	8.83	39.90	8.88	↑		1.31	0.2229	Not Significant
NSS Score	10	9	43.70	6.60	43.80	7.05	↑		0.43	0.6783	Not Significant
Serum Testoterone (ng/dL)	10	9	269.86	276.98	269.94	277.41	↑		0.17	0.8669	Not Significant



OVERALL ASSESSMENT OF TRIAL DRUG AND PLACEBO

8. Overall Assessment of results after treatment				
Overall Assessment	Trial Group		Placebo Group	
	No. of Patients	Percentage	No. of Patients	Percentage
Excellent	30	79%	0	00%
Good	6	16%	0	00%
Satisfactory	2	05%	3	30%
Unsatisfactory	0	00%	7	70%



ASSESSMENT OF ADVERSE EFFECT OF TRIAL DRUG AND PLACEBO

No adverse effect was found in both trial and placebo group during and after treatment.

OBSERVATION HIGHLIGHTS

- The study included both male (36 nos.) and female (12 nos.) patients. But males dominated female patients.
- The Study included patients in the age limit of 30 to 60 years (both inclusive). Patients in the age group of 41 – 50 years were maximum (14 & 5) and in the age group of 50 – 60 years were minimum (10 & 2) both in TG & PG.
- HSDD was found to be well distributed among different occupation. However patients with Executive and intellectual field work were found to be maximum (18 nos.) in TG & people with House work were found to be maximum (5 nos.) in PG.
- HSDD affect all types of Socio-economic classes of population Medium class being the maximum (65.78% in TG & 70% in PG) followed by low and high classes.

- It was alarming that 5.26 % patients in the TG and 20 % patients in the PG were having some or the other addiction. However Tobacco (42.11% in TG) users were maximum followed by No addiction and alcohol users.

- Vigor-100 Stamina (Trial Drug) was found effective in increasing the SDI-2 score from 38.82 to 63.34 and the results was found to be extremely statistically significant ($p < 0.0001$). But the Placebo drug was not effective in increasing the SDI-2 score from 39.50 to 39.90 and the result was insignificant (p –value, 0.2229).

- Vigor-100 Stamina (Trial Drug) was found effective in increasing the NSS score from 41.34 to 67.73 and the results was found to be extremely statistically significant ($p < 0.0001$). But the Placebo drug was not effective in increasing the NSS score from 43.70 to 43.80 and the result was insignificant (p –value, 0.6783).

- Vigor-100 Stamina (Trial Drug) was also found effective in increasing the Serum Testosterone level from 344.67 ng/dl to 525.99ng/dl and the results was found to be extremely statistically significant ($p < 0.0007$). But the Placebo drug was not effective in increasing the Serum Testosterone level from 269.86ng/dl to 277.41ng/dl and the result was insignificant (p –value, 0.8669).

- It also increase the desire, frequency, quality of orgasm and ability in the trial group as follows-

    - 93 % of the subjects in the Trial Group (TG) experienced significantly increased libido by the completion of therapy.

    - 82 % of the subjects were having increased frequency of sexual activity as compared to the “Before Treatment” phase.

    - 91 % of the subjects experienced greater intensity of sexual arousal during and after completion of the therapy.

    - 89 % of the male subjects had better erection during sexual events.

    - 95 % of the subjects experienced a reasonably satisfying duration of sexual activity.

    - 90 % of the subjects reported a much better quality of orgasm.

    - 97 % of the subjects experienced a better mood after completion of sexual activity.

    - 86 % of the subjects were able to create a balance between what they gave and what they received from their partner during sexual act.

- On overall assessment of the effectiveness of Vigor-100 stamina & Placebo in HSDD we got the following results Vigor-100 stamina gave Excellent results in 79 % cases, Good result in 16 % cases, Satisfactory results in 5 % cases and Unsatisfactory results in 00 % cases where as Placebo gave excellent results in 00 % cases, Good result in 00 % cases, Satisfactory results in 30 % cases and Unsatisfactory results in 70 % cases.
- On analysing the incidence of adverse effects we got, Neither Vigor-100 Stamina nor does the Placebo produce any adverse effect. So the trial is safe without any complication and with a successful result.

DISCUSSION

The male patients dominated the female patients in the study. This may be due to the reasons that males are more addicted to tobacco & alcohol and their addction is more conducive for stress and result in Hypo active Sexual Desire Disorder(HSDD) . Since in the state like Odisha males get better medical facility than females, their footfall might have been more during the trial period also female may not came to physician for this disease as they may feel shy to communicate this. Small sample size may be a cause that female patients are less in numbers.

Patients in the age group of 40 – 50 were maximum in the trial indicating that HSDD is more prevalent in this age group. This may be due to the fact that these years in life are more stressful years due to late marriage and also due to joint family they may not give sufficient time for sexual activity. So there is every chance of altered dietary habits and getting addicted to tobacco or alcohol which might have facilitated the progression of HSDD.

The Executive peoples and people with intellectual field work were more in number in this trial. Their Stressful life style (as they are not satisfied in their job) may be held responsible for accelerating HSDD.

Most of the patients were having addiction of Tobacco and alcohol. High incidence of tobacco & alcohol users proves that these are potential risk factors for HSDD.

Medium socio-economic people are more prone for HSDD as they cannot fulfil the all needs properly and having stress in life. As stress is the prime factor, so they are attribute to HSDD.

Vigor-100 Stamina (Trial Drug) was found effective in increasing the SDI-2 score, NSS Score and Serum Testosterone level as compare to the Placebo drug. Trial Drug increases all the criteria remarkable but Placebo increase very less or negligible. However the little change is due to the effect of Patients counselling, education and effect of the Placebo.

The overall effect of Vigor-100 Stamina and Placebo can't be comparable as Vigor-100 stamina shows remarkable excellent result but the Placebo shows very less satisfactory effects.

As per safety profile, both are safe without any adverse effect and any organic effects like alter liver function and renal functions.

Considering the effectiveness both Vigor-100 Stamina and Placebo in managing HSDD, we can say that the former has greater effect over the later. Vigor-100 Stamina has unique ability to manage HSDD without causing any adverse effect or deleterious effect on the vital organs.

Possible Mode of Action of Vigor-100 Stamina

The trial drug poly herbal compound (Vigor-100-stamina) having such potency containing some aphrodisiac drugs like- Kapikachhu, Shilajit, Mushli, Aswagandha, Samudra sosha, Jaiphala, Jaipatri, Dalchini, Akarakara, Lavanga, Keshara, Louha bhasma and Swarna bhasma etc. and processed by triturating with Brahmi juice, Mulethi decoction, Chandan decoction, Satavari juice and Beetle juice.

Kapikachhu, Akarakara, Jaipatri, Shilajit, Musali, Samudrasosha, Keshar having aphrodisiac properties which might be able to enhance the Serum testosterone level. These individuals' drugs have also proven earlier as aphrodisiac by various experimental and human trials.

The drugs like Aswagandga, Swarna bhasma, Satavari, Mulethi, Brahmi are very much effective in case of Stress and stress related disorders. As the disease HSDD is mainly related to stress, so this drugs successfully control HSDD.

And the poly herbal compound is very effective by the synergetic actions of all these drugs together.

CONCLUSION

As per the results of this study, Vigor-100 Stamina (Trial Drug) was found effective in increasing the SDI-2 score, NSS Score and Serum Testosterone level as compare to the Placebo drug. Trial Drug increases all the criteria remarkable but Placebo increase very less or negligible. The trial drug also increase all the criteria like frequency, quality of orgasm, ability and desire as compare to the placebo. Since Vigor-100 Stamina doesn't produce any adverse effects, therefore Vigor-100 Stamina would definitely be a better and safer choice in managing Hypoactive Sexual Desire Disorder (HSDD).

Further it is advice to continue the follow up study.

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